REMARKS

This paper is submitted in response to an office action dated February 12, 2008, which was a final office action. A response is due August 12, 2008, by virtue of the attached petition and fee for a three-month extension of time to respond. This response is accompanied by a Request for Continued Examination.

A. Status of the Claims

Claims 24-32, 43-53 and 64 were pending at the time of the office action and stand rejected under 35 U.S.C. § 103 (a). Applicants respectfully request reconsideration of the rejection in view of the current response.

B. Rejection of Claims under 103(a)

Claims 24-32, 43-53 and 64 66 were rejected under 35 U.S.C. 103(a) as allegedly being rendered obvious over Cham et al. 1990 either alone or in combination with U.S. Patent 4,053,591. Applicants traverse the rejections and address the rejections with respect to the method claims and the composition claims separately.

Claims 24-32, 43-53 and 64 are rejected over Cham et al. The examiner maintains that Cham et al. disclose a composition comprising glycoalkaloids useful for treating cancer; that rhamnose inhibits efficacy of BEC and that the aglycone solasodine is not effective against murine S180. Accordingly, the Examiner asserts that the skilled person would have been motivated to remove rhamnose and aglycones from the BEC in order to improve BEC efficacy.

U.S. Patent 4,053,591 is cited in combination with Cham et al against claims 30, 31, 51 and 52 as teaching removal of an aglycone using chloroform purification process.

In response to the Applicants arguments, the Examiner noted "At the time the claimed invention was made rhamnose was know to effect [sic] the efficacy of BEC. The degradation of BEC, which results in free rhamnose occurs over time. Thus it is not clear how much if any rhamnose was present in the composition tested by Cham et al."

The Examiner simply makes the assertion that rhamnose is present as a degradation product without providing any basis for this being known in the prior art. But

then goes on to say that it is not clear how much if any is present. Such an unsupported unsupported statement cannot properly establish obviousness of the present claims. Applicants respectfully submit that because the Cham paper does not disclose the fact that the glycoalkaloids necessarily degrade to the aglycone and intact rhamnose and that these degradation products inhibit the activity of the glycoalkaloid then there can be no motivation to remove the degradation products.

The Examiner appears to be arguing that there must necessarily have been some rhamnose inherently present in the BEC composition due to degradation. The Examiner has presented no evidence to show that this is indeed the case. As applicants noted previously, there is no mention anywhere in Cham of the presence of rhamnose as a result of degradation. The only rhamnose tested in Cham **was exogenously added.** The conclusion reached by the examiner is based on an assumption that the BEC disclosed in Cham is not effective because it contains rhamnose as a degradation product. The Examiner's conclusion is wrong. The rhamnose discussed in the Cham paper is not a degradation product of the BEC in the composition being used but is in fact added to the BEC composition. In the absence of disclosure of rhamnose present as a degradation product, an obviousness argument cannot be sustained. Indeed, the Examiner's own rejection states "it is not clear how much **if any** rhamnose was present in the composition tested by Cham et al." Even the examiner's rejection shows that presence of rhamnose as a degradation product is not clear from the Cham reference. As such, the examiner has failed to establish obviousness in view of Cham.

The teachings of Cham only stretch to teaching that it is undesirable to ***add*** rhamnose to the BEC composition, Cham et al says nothing about the BEC composition itself being ineffective. Applicants again reiterate that it is the disclosure of the present application that first taught that degradation of BEC leads to accumulation of rhamnose and other sugars and that this accumulation makes the BEC composition less effective as a therapeutic agent. Hence, the present application, for the first time, presents the desirability of further purifying BEC glycoalkaloid compositions to remove essentially all the free sugars that appear in the composition as a result of glycoalkaloid degradation.

The applicants respectfully request reconsideration of the rejection under 35 U.S.C. §103(a).

Respectfully Submitted,

HOWREY LLP

By /Nabeela R. McMillian, #43,363/
Nabeela R. McMillian, Ph.D.
Registration No.: 43,363

Dated: August 7, 2008

CUSTOMER NUMBER 22930
C/O IP DOCKETING DEPARTMENT
HOWREY, LLP
2941 FAIRVIEW PARK DR. STE 200
FALLS CHURCH, VA 22042-9922
Telephone No.: (703) 663-3600
Facsimile No.: (202) 383-7195